



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 23 2000 5 00 OCT 25 P2:22

Mr. Vincent De Stefano
Associate Director, Regulatory Affairs
Novartis Consumer Health, Inc.
560 Morris Avenue
Summit, New Jersey 07901-1312

Dear Mr. De Stefano:

This is in response to your letters to the Food and Drug Administration (FDA), dated October 4, 2000, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Novartis Consumer Health, Inc. is making the following claims, among others, for the following products:

Resource® Wellness AllerPro

- "Allergy Formula - Helps Moderate The Body's Reaction to External Allergens"
- "For Whom? People looking to moderate their body's reactions to external allergens"
- "To do What? Helps lessen discomfort commonly associated with allergies"
- "...help moderate discomforts commonly associated with allergies"
- "...improve the body's defenses against irritating allergies"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product, including the name of the product (i.e., AllerPro), suggest that it is intended to treat, prevent, or mitigate diseases, namely allergies. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET.406

Page 2 - Mr. Vincent De Stefano

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, New Jersey District Office, Compliance Branch, HFR-MA240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Nickerson, Dorsey)
f/t:rjm:HFS-811:10/20/00:72819.adv:disc51

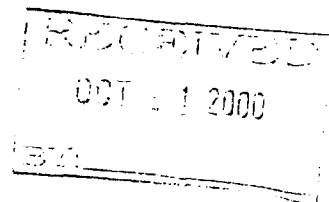


Novartis Consumer Health, Inc.
560 Morris Avenue
Summit, NJ 07901-1312

Main Number: 908-598-7600
Fax: 908-273-2869

October 4, 2000

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W. (HFS-450)
Washington, D.C. 20204



Re: Section 403(r)(6) Notification

Dear Sir or Madam,

In accordance with the requirement of Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Novartis Consumer Health, Inc. notifies the Food and Drug Administration that it has, within the past thirty (30) days, begun using the following phrase and statement:

Allergy Formula – Helps Moderate The Body's Reaction to External Allergens

For Whom? People looking to moderate their body's reactions to external allergens.

To Do What? Helps lessen discomfort commonly associated with allergies.

Xanthium Sibiricum, Gardenia Jasminodes, Chrysanthemum Morifolium: Natural fruit and flower extracts that help moderate discomforts commonly associated with allergies.

Scutellaria Baicalensis: Natural root extract that helps improve the body's defenses against irritating allergies.

on the following product:

Resource® Wellness AllerPro

The statements of nutritional support are based on scientific literature which render the statements substantiated, truthful and non-misleading. The information submitted herein is a complete and accurate representation of the product named.

Sincerely,

Novartis Consumer Health, Inc.

Vincent De Stefano
Associate Director, Regulatory Affairs

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**ReSource®
Wellness**

For Whom?
People looking to moderate their body's reactions
to external allergens*

To Do What?
Helps lessen discomfort commonly associated
with allergies*

ALLERGY FORMULA

A soothing, natural blend of traditional
botanical extracts and fruit extracts

AllerPro™

Xanthium sibiricum, gardenia jasminoides, chrysanthemum morifolium
Natural fruit and flower extracts that help moderate discomforts commonly
associated with allergies*

Scutellaria baicalensis
Natural root extract that helps improve the body's defenses against
irritating allergens*

* These statements have not been evaluated by the Food and
Drug Administration. This product is not intended to
diagnose, treat, cure or prevent any disease.



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EXP

LOT NO

DIRECTIONS: Take 2 or 3 Capsules once per day.

Supplement Facts

Serving Size: 2 Capsules (1396 mg)
Servings Per Container: 30

Amount Per Serving	% Daily Value**
Proprietary Blend (698 mg/capsule)	
Psoralea corylifolia (Fruit Extract)	**
Xanthium sibiricum (Fruit Extract)	**
Scutellaria baicalensis (Root Extract)	**
Gardenia jasminoides (Fruit Extract)	**
Bupleurum chinense (Root Extract)	**
Chrysanthemum morifolium (Flower Extract)	**
Areca catechu (Husk Extract)	**
Schisandra chinensis (Fruit Extract)	**
Ziziphus spinosa (Seed Extract)	**
Schizonepeta tenuifolia (Flower Extract)	**
Plantago asiatica (Seed Extract)	**

** Daily Value not established.

Other Ingredients: Gelatin, Maltodextrin, Magnesium
Stearate, Silicon Dioxide, Sodium Lauryl Sulfate,
Polysorbate 80

WARNINGS: FOR ADULTS ONLY. Keep out of reach of
children. Consult your health professional before using if
you are pregnant, nursing a baby, or are taking any
prescription medications. Do not use if you have an ulcer.
May cause photosensitivity.

Store in a cool, dry place.
Do not use if imprinted seal under cap is missing or broken.

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**ReSource®
Wellness**

AllerPro™

Dietary Supplement
Traditional Herbs & Fruit Extracts

ALLERGY FORMULA

NEW!

**ReSource®
Wellness**

AllerPro™

Dietary Supplement
Traditional Herbs & Fruit Extracts

ALLERGY FORMULA

Helps Moderate
The Body's Reactions
To External Allergens*

60 CAPSULES



Advanced Health Maintenance Formulas From Novartis

Our Commitment To Quality
ReSource® Wellness formulas are created by Novartis –
a leading developer of nutrition and self-medication
products to consumers, hospitals, and health care
facilities for over 50 years. Novartis is committed to
creating superior quality supplements to meet your health
maintenance needs. All our products are backed by
toll-free assistance from nutritional experts to help you
make informed decisions.

The ReSource® Wellness Commitment
At Novartis, we extend our quality commitment to every
ReSource® Wellness product by performing a
BioCheck™ certification.

BioCheck™ Certified



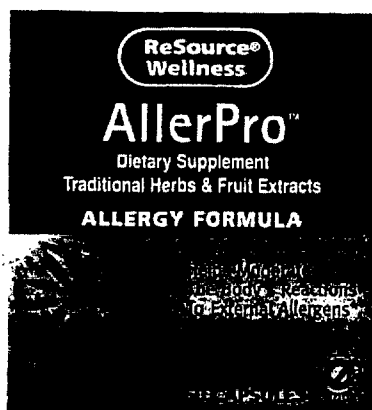
- ✓ **QUALITY** Manufacturing process assures
product quality.
- ✓ **SAFETY** Product passes scientific review for
safety of use.
- ✓ **BENEFIT** Scientific literature supports
effectiveness for use indicated.

Call toll-free 1-877-939-3556
8AM-5PM E.T. to speak to our nutritional experts,
or visit our website at
www.resourcewellness.com

NOVARTIS

Distributed by: Novartis Consumer Health, Inc.
Summit, NJ 07901-1312 ©2000

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DIRECTIONS: Take 2 or 3 Capsules once per day.

Supplement Facts

Serving Size: 2 Capsules (1398 mg)
Servings Per Container: 30

Amount Per Serving	% Daily Value**
Proprietary Blend (698 mg/capsule)	
Psoralea corylifolia (Fruit Extract)	**
Xanthium subincum (Fruit Extract)	**
Scutellaria baicalensis (Root Extract)	**
Gardenia jasminoides (Fruit Extract)	**
Bupleurum chinenses (Root Extract)	**
Chrysanthemum montolium (Flower Extract)	**
Areca catechu (Husk Extract)	**
Schisandra chinensis (Fruit Extract)	**
Ziziphus spinosa (Seed Extract)	**
Schizonepeta tenuifolia (Flower Extract)	**
Plantago asiatica (Seed Extract)	**

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Other Ingredients: Gelatin, Maltodextrin, Magnesium Stearate, Silicon Dioxide, Sodium Lauryl Sulfate, Polysorbate 80

WARNINGS: FOR ADULTS ONLY. Keep out of reach of children. Consult your health professional before using if you are pregnant, nursing a baby, or are taking any prescription medications. Do not use if you have an ulcer. May cause photosensitivity.

Store in a cool, dry place.

Do not use if imprinted seal under cap is missing or broken.

BioCheck™ Certified

- ✓ **QUALITY** Manufacturing process assures product quality.
- ✓ **SAFETY** Product passes scientific review for safety of use.
- ✓ **BENEFIT** Scientific literature supports effectiveness for use indicated.

Call toll-free 1-877-939-3556 8AM-5PM E.T.
to speak to our nutritional experts, or visit our website at
www.resourcewellness.com

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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